

TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-18-0169

Number: P-18-0169

TSCA Section 5(a)(3) Determination: The new chemical substance is not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:

Generic: Propanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl-, polymer with dimethyl carbonate, 1,6-hexanediol, diamine and 1,1'-methylenebis[4-isocyanatocyclohexane], acrylate-blocked, compds. with triethylamine

Conditions of Use (intended, known, or reasonably foreseen)¹:

Intended conditions of use (generic): Manufacture for use as a protective coating, consistent with the manufacturing, processing, use, distribution, and disposal information described in the PMN.

Known conditions of use: Applying such factors as described in footnote 1, EPA evaluated whether there are known conditions of use and found none.

Reasonably foreseen conditions of use: Applying such factors as described in footnote 1, EPA evaluated whether there are reasonably foreseen conditions of use and found none.

Summary: The new chemical substance is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, based on the risk assessment presented below. Although EPA estimated that the new chemical substance could be very persistent, the new chemical substance has low potential for bioaccumulation, such that repeated exposures are not expected to be cumulative. EPA estimates that the new chemical substance has low environmental hazard and potential for the following human health hazards: irritation, sensitization, and developmental toxicity and neurotoxicity. EPA concludes that the new chemical substance is not likely to present an unreasonable risk under the conditions of use.

¹ Under TSCA § 3(4), the term “conditions of use” means “the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” In general, EPA considers the intended conditions of use of a new chemical substance to be those identified in the section 5(a) notification. Known conditions of use include activities within the United States that result from manufacture that is exempt from PMN submission requirements. Reasonably foreseen conditions of use are future circumstances, distinct from known or intended conditions of use, under which the Administrator expects the chemical substance to be manufactured, processed, distributed, used, or disposed of. The identification of “reasonably foreseen” conditions of use will necessarily be a case-by-case determination and will be highly fact-specific. Reasonably foreseen conditions of use will not be based on hypotheticals or conjecture. EPA’s identification of conditions of use includes the expectation of compliance with federal and state laws, such as worker protection standards or disposal restrictions, unless case-specific facts indicate otherwise. Accordingly, EPA will apply its professional judgment, experience, and discretion when considering such factors as evidence of current use of the new chemical substance outside the United States, evidence that the PMN substance is sufficiently likely to be used for the same purposes as existing chemical substances that are structurally analogous to the new chemical substance, and conditions of use identified in an initial PMN submission that the submitter omits in a revised PMN. The sources EPA uses to identify reasonably foreseen conditions of use include searches of internal confidential EPA PMN databases (containing use information on analogue chemicals), other U.S. government public sources, the National Library of Medicine’s Hazardous Substances Data Bank (HSDB), the Chemical Abstract Service STN Platform, REACH Dossiers, technical encyclopedias (e.g., Kirk-Othmer and Ullmann), and Internet searches.

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Fate: Environmental fate is the determination of which environmental compartment(s) a chemical moves to, the expected residence time in the environmental compartment(s) and removal and degradation processes. Environmental fate is an important factor in determining exposure and thus in determining whether a chemical may present an unreasonable risk. EPA estimated a number of physical/chemical and fate properties of this new chemical substance using data on high molecular weight polymers. The new chemical substance is estimated to be removed during wastewater treatment with an efficiency of 90% via sorption. For the new chemical substance, removal by biodegradation is estimated to be negligible based on data for high molecular weight polymers. Sorption to sludge is estimated to be strong, and sorption to soil and sediment is estimated to be very strong, resulting in negligible migration to groundwater for the new chemical substance. Volatilization to air is estimated to be negligible for the new chemical substance based on data for high molecular weight polymers. Overall, these estimates are indicative of low potential for this chemical substance to volatilize into the air and a low potential for this chemical to migrate into ground water.

Persistence²: Persistence is relevant to whether a new chemical substance is likely to present an unreasonable risk because chemicals that are not degraded in the environment at rates that prevent substantial buildup in the environment, and thus increase potential for exposure, may present a risk if the substance presents a hazard to human health or the environment. Based on data for high molecular weight polymers, EPA estimates the anaerobic and aerobic biodegradation half-lives of the new chemical substance to be greater than six months. These estimates for biodegradation indicate that the new chemical substance will be very persistent in aerobic environments (e.g., surface water) or anaerobic environments (e.g., sediment).

Bioaccumulation³: Bioaccumulation is relevant to whether a new chemical substance is likely to present an unreasonable risk because substances that bioaccumulate in aquatic and/or terrestrial species pose the potential for elevated exposures to humans and other organisms via food chains. The new chemical substance has low bioaccumulation potential based on high molecular weight polymers, large predicted molecular volume and low water solubility which limit bioavailability and bioaccumulation. Although EPA estimated that the new chemical substance could be very persistent, the new chemical substance has low potential for bioaccumulation such that repeated exposures are not expected to cause food chain effects via accumulation in exposed organisms.

² Persistence: A chemical substance is considered to have limited persistence if it has a half-life in water, soil or sediment of less than 2 months or there are equivalent or analogous data. A chemical substance is considered to be persistent if it has a half-life in water, soil or sediments of greater than 2 months but less than or equal to 6 months or if there are equivalent or analogous data. A chemical substance is considered to be very persistent if it has a half-life in water, soil or sediments of greater than 6 months or there are equivalent or analogous data. (64 FR 60194; November 4, 1999)

³ Bioaccumulation: A chemical substance is considered to have a low potential for bioaccumulation if there are bioconcentration factors (BCF) or bioaccumulation factors (BAF) of less than 1,000 or there are equivalent or analogous data. A chemical substance is considered to be bioaccumulative if there are BCFs or BAFs of 1,000 or greater and less than or equal to 5,000 or there are equivalent or analogous data. A chemical substance is considered to be very bioaccumulative if there are BCFs or BAFs of 5,000 or greater or there are equivalent or analogous data. (64 FR 60194; November 4 1999)

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Human Health Hazard⁴: Human health hazard is relevant to whether a new chemical substance is likely to present an unreasonable risk because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance.

EPA estimated the human health hazard of this new chemical substance based on its estimated physical/chemical properties, analogue data and information in the TSCA New Chemicals Category for Acrylates/Methacrylates⁵. For this new chemical substance, absorption of the high molecular weight species (> 1000) is estimated to be nil by all routes and absorption of the low molecular weight fractions (0.5% < 1000 and 0.5% < 500) is estimated to be poor all routes based on physical/chemical properties.

For the new chemical substance, EPA identified dermal and respiratory irritation and sensitization as hazards based on the presence of acrylate moieties and information in the Safety Data Sheet (SDS). EPA also identified developmental toxicity, neurotoxicity and irritation hazards based on the presence of triethylamine. EPA quantitatively assessed the new chemical substance using test data on an analogue, dimethylcyclohexylamine. A NOAEL of 8.5 mg/kg-bw/day was identified for developmental toxicity in a Combined Repeated Dose Toxicity Study with Reproduction/Developmental Toxicity Screening Test (OECD 422). This NOAEL was used to derive exposure-route and population-specific points of departure for quantitative risk assessment, described below.

Environmental Hazard⁶: Environmental hazard is relevant to whether a new chemical substance is likely to present unreasonable risk because the significance of the risk is dependent

⁴ A chemical substance is considered to have low human health hazard if effects are observed in animal studies with a No Observed Adverse Effect Level (NOAEL) equal to or greater than 1,000 mg/kg/day or if there are equivalent data on analogous chemical substances; a chemical substance is considered to have moderate human health hazard if effects are observed in animal studies with a NOAEL less than 1,000 mg/kg/day or if there are equivalent data on analogous chemical substances; a chemical substance is considered to have high human health hazard if there is evidence of adverse effects in humans or conclusive evidence of severe effects in animal studies with a NOAEL of less than or equal to 10 mg/kg/day or if there are equivalent data on analogous chemical substances. EPA may also use Benchmark Dose Levels (BMDL) derived from benchmark dose (BMD) modeling as points of departure for toxic effects. See <https://www.epa.gov/bmds/what-benchmark-dose-software-bmds>. Using this approach, a BMDL is associated with a benchmark response, for example a 5 or 10 % incidence of effect. The aforementioned characterizations of hazard (low, medium, high) would also apply to BMDLs. In the absence of animal data on a chemical or analogous chemical substance, EPA may use other data or information such as from in vitro assays, chemical categories (e.g., Organization for Economic Co-operation and Development, 2014 Guidance on Grouping of Chemicals, Second Edition. ENV/JM/MONO(2014)4. Series on Testing & Assessment No. 194. Environment Directorate, Organization for Economic Co-operation and Development, Paris, France. ([http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2014\)4&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)4&doclanguage=en))), structure-activity relationships, and/or structural alerts to support characterizing human health hazards.

⁵ TSCA New Chemicals Program (NCP) Chemical Categories. <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemical-categories-used-review-new>.

⁶ A chemical substance is considered to have low ecotoxicity hazard if the Fish, Daphnid and Algae LC50 values are greater than 100 mg/L, or if the Fish and Daphnid chronic values (ChVs) are greater than 10.0 mg/L, or there are not effects at saturation (occurs when water solubility of a chemical substance is lower than an effect concentration), or the log Kow value exceeds QSAR cut-offs. A chemical substance is considered to have moderate ecotoxicity hazard if the lowest of the Fish, Daphnid or Algae LC50s is greater than 1 mg/L and less than 100 mg/L, or where the Fish or Daphnid ChVs are greater than 0.1 mg/L and less than 10.0 mg/L. A chemical substance is considered to have

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upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. EPA determined environmental hazard for this new chemical substance based on SAR predictions for polyanionic polymers (special class within ECOSAR v.2.0). Acute toxicity values estimated for fish, aquatic invertebrates and algae are all > 100 mg/L. Chronic toxicity values estimated for fish, aquatic invertebrates, and algae are all > 10 mg/L. These toxicity values indicate that the new chemical substance is expected to have low environmental hazard. Application of assessment factors of 5 and 10 to acute and chronic toxicity values, respectively, results in acute and chronic concentrations of concern of 20 mg/L (20,000 ppb) and 1 mg/L (1,000 ppb), respectively.

Exposure: The exposure to a new chemical substance is potentially relevant to whether a new chemical substance is likely to present unreasonable risks because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance.

EPA estimates occupational exposure and environmental releases of the chemical substance under the intended conditions of use described in the PMN using ChemSTEER (Chemical Screening Tool for Exposures and Environmental Releases; <https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases>). EPA uses EFAST (the Exposure and Fate Assessment Screening Tool; <https://www.epa.gov/tsca-screening-tools/e-fast-exposure-and-fate-assessment-screening-tool-version-2014>) to estimate general population, consumer, and environmental exposures.

EPA considers workers to be a potentially exposed or susceptible subpopulation (PESS) on the basis of greater exposure potential compared to the general population. EPA also considers PESS in conducting general population drinking water exposures by evaluating risks associated with water intake rates for multiple age groups, ranging from infants to adults. EPA considers consumers of specific products to be a potentially exposed or susceptible subpopulation on the basis of greater exposure potential compared to the general population who do not use specific products.

For this new chemical assessment, EPA assessed exposure to workers via the inhalation and dermal routes. Releases to water, air and landfills were estimated. Exposure to the general population was assessed via drinking water. Consumer exposures were not assessed because consumer uses were not identified as conditions of use. For the new chemical substance, exposures from fish ingestion were not assessed because the chemical is not estimated to be persistent or bioaccumulative. Exposures to the general population via inhalation were not estimated because releases are expected to be negligible (below modeling thresholds).

Risk Characterization: EPA applies a margin of exposure approach to calculate potential human health risks of new chemicals. A benchmark (acceptable) margin of exposure is derived

high ecotoxicity hazard, or if either the Fish, Daphnid or Algae LC50s are less than 1 mg/L, or any Fish or Daphnid ChVs is less than 0.1 mg/L (Sustainable Futures <https://www.epa.gov/sustainable-futures/sustainable-futures-p2-framework-manual>).

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by applying uncertainty factors for the following types of extrapolations: intra-species extrapolation ($UF_H = 10$ to account for variation in sensitivity among the human population), inter-species extrapolation ($UF_A = 10$ to account for extrapolating from experimental animals to humans) and LOAEL-to-NOAEL extrapolation ($UF_L = 10$ to account for using a LOAEL when a NOAEL is not available). Hence, in the New Chemicals Program, a benchmark MOE is typically 100 and 1000 when NOAELs and LOAELs, respectively, are used to identify hazard. When allometric scaling or pharmacokinetic modeling is used to derive an effect level, the UF_H may be reduced to 3, for a benchmark MOE of 30. The benchmark MOE is used to compare to the MOE calculated by comparing the toxicity NOAEL or LOAEL to the estimated exposure concentrations. When the calculated MOE is equal to or exceeds the benchmark MOE, the new chemical substance is not likely to present an unreasonable risk. EPA assesses risks to workers considering engineering controls described in the PMN but in the absence of personal protective equipment such as gloves and respirators. If risks are preliminarily identified, EPA then considers whether the risks would be mitigated by the use of PPE (e.g., impervious gloves, respirator).

Risks to human health for the new chemical substances were evaluated using the route-specific effect level (i.e., NOAEL) described above. Risks were not identified for workers for systemic toxicity (developmental toxicity and neurotoxicity) from inhalation exposure (MOE = 331; benchmark MOE = 100). When poor dermal absorption was assumed in the absence of glove use, risks were not identified for workers for systemic toxicity (developmental toxicity and neurotoxicity) from dermal exposure (MOE = 149; benchmark MOE = 100).

Irritation and sensitization hazards to workers via inhalation and dermal contact were identified. Risks for these endpoints were not quantified due to a lack of dose-response for these hazards. However, exposures can be mitigated by the use of appropriate personal protective equipment (PPE), including impervious gloves, eye protection and respiratory protection (respirators with assigned protection factors (APFs) of 1000 and 50 for spray applications and non-spray applications, respectively). EPA expects that workers will use appropriate PPE consistent with the Safety Data Sheet prepared by the new chemical submitter, in a manner adequate to protect them.

For the new chemical substance, risks were not identified for the general population for systemic toxicity (developmental toxicity and neurotoxicity) via drinking water ingestion (MOE_{adult} = 280,306; MOE_{infant} = 67,220; benchmark MOE = 100). For the new chemical substance, risks were not identified for the general population for sensitization and irritation via drinking water ingestion. Risks for these hazard endpoints were not quantified due to a lack of dose-response for this hazard. These effects are considered less likely via the drinking water route at the estimated exposures, which $\leq 7.98 \times 10^{-4}$ mg/kg-bw/day.

Risks to the environment were evaluated by comparing estimated surface water concentrations with the acute and chronic concentrations of concern. Risks to the environment were not identified based on low hazard.

Because worker exposures can be controlled by PPE, no unreasonable risks to the general population or environment were identified, and there are no expected exposures to consumers,

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EPA has determined that the new chemical substance is not likely to present unreasonable risk to human health or the environment under the conditions of use.

02/28/2019
Date:

/s/
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Office of Pollution Prevention and Toxics